



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jerrold P. Weiss et al. Art Unit : 1654
Serial No. : 10/715,876 Examiner : Unknown
Filed : November 17, 2003
Title : ISOLATED COMPLEXES OF ENDOTOXIN AND MD-2

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants request consideration of the references listed on the attached PTO-1449 form. Under 37 C.F.R. § 1.98 (a)(2)(ii), only copies of foreign patent documents and/or non-patent literature are enclosed. Copies of any listed U.S. patents or U.S. patent application publications can be provided upon request.

This statement is being filed before the receipt of a first Office Action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: 14 February 2005

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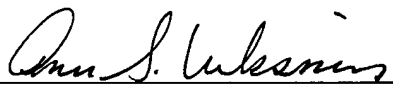
The following correspondence relating to this application is enclosed for filing:

1. Information Disclosure Statement (1 page);
2. Form PTO-1449 (6 pages);
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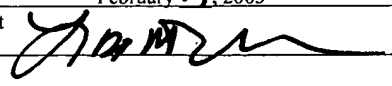

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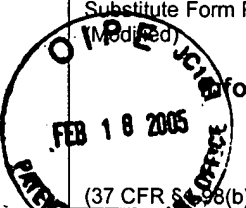
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	Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17023-030001	Application No. 10/715,876
	Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR § 1.98(b))			Applicant Jerrold P. Weiss et al.
				Filing Date November 17, 2003

U.S. Patent Documents

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	3,561,444	02/09/71	Boucher			
	AB	3,703,173	11/21/72	Dixon			
	AC	4,624,251	11/25/86	Miller			
	AD	4,635,627	01/13/87	Gam			
	AE	4,962,091	10/09/90	Eppstein et al.			

Foreign Patent Documents or Published Foreign Patent Applications

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AF	WO 94/07529	04/14/94	PCT				
	AG	WO 97/19688	06/05/97	PCT				

Other Documents (include Author, Title, Date, and Place of Publication)

Examiner Initial	Desig. ID	Document
	AH	Abreu et al., "TLR4 and MD-2 Expression Is Regulated by Immune-mediated Signals in Human Intestinal Epithelial Cells," <u>J. Biol. Chem.</u> , 2002, 277(23):20431-20437
	AI	Abreu et al., "Decreased Expression of Toll-Like Receptor-4 and MD-2 Correlates with Intestinal Epithelial Cell Protection Against Dysregulated Proinflammatory Gene Expression in Response to Bacterial Lipopolysaccharide," <u>J. Immunol.</u> , 2001, 167:1609-1617
	AJ	Akashi et al., "Lipopolysaccharide Interaction with Cell Surface Toll-like Receptor 4-MD-2: Higher Affinity than That with MD-2 or CD14," <u>J. Exp. Med.</u> , 2003, 198(7):1035-1042
	AK	Akashi et al., "Cutting Edge: Cell Surface Expression and Lipopolysaccharide Signaling Via the Toll-Like Receptor 4-MD-2 Complex on Mouse Peritoneal Macrophages," <u>J. Immunol.</u> , 2000, 164:3471-3475
	AL	Altschul et al., "Basic Local Alignment Search Tool," <u>J. Mol. Biol.</u> , 1990, 215:403-410
	AM	Altschul et al., "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs," <u>Nucl. Acids Res.</u> , 1997, 25(17):3389-3402
	AN	Anderson et al., "A simple method for the rapid generation of recombinant adenovirus vectors," <u>Gene Ther.</u> , 2000, 7:1034-1038
	AO	Anderson, "Toll signaling pathways in the innate immune response," <u>Curr. Opin. Immunol.</u> , 2000, 12:13-19
	AP	Arbour et al., "TLR4 mutations are associated with endotoxin hyporesponsiveness in humans," <u>Nat. Genet.</u> , 2000, 25:187-191
	AQ	Bacchi et al., "Polyamine metabolism in the Microsporidia," <u>Biochemical Society Transactions</u> , 2003, 31(2):420-423
	AR	Bals et al., "Human β -Defensin 2 Is a Salt-sensitive Peptide Antibiotic Expressed in Human Lung," <u>J. Clin. Invest.</u> , 1998, 102(5):874-880

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Other Documents (include Author, Title, Date, and Place of Publication)		
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	AS	Bandi et al., "Nontypeable <i>Haemophilus influenzae</i> in the Lower Respiratory Tract of Patients with Chronic Bronchitis," <u>Am. J. Respir. Crit. Care Med.</u> , 2001, 164:2114-2119
	AT	Becker et al., "CD14-dependent Lipopolysaccharide-induced β -Defensin-2 Expression in Human Tracheobronchial Epithelium," <u>J. Biol. Chem.</u> , 2000, 275(38):29731-29736
	AU	Beutler and Poltorak, "Sepsis and evolution of the innate immune response," <u>Crit. Care Med.</u> , 2001, 29(7)(Suppl.):S2-S7
	AV	Beutler and Rietschel, "Innate immune sensing and its roots: the story of endotoxin," <u>Nat. Rev. Immunol.</u> , 2003, 3:169-176
	AW	Bustin "Absolute quantification of mRNA using real-time reverse transcription polymerase chain reaction assays," <u>J. Mol. Endocrinol.</u> , 2000, 25:169-193
	AX	Corpet, "Multiple sequence alignment with hierarchical clustering," <u>Nucl. Acids Res.</u> , 1988, 16(22):10881-10890
	AY	Correia et al., "Lipopolysaccharide Is in Close Proximity to Each of the Proteins in Its Membrane Receptor Complex," <u>J. Biol. Chem.</u> , 2001, 276(24):21129-21135
	AZ	Denning et al., " <i>Pseudomonas</i> Pyocyanin Increases Interleukin-8 Expression by Human Airway Epithelial Cells," <u>Infect. Immun.</u> , 1998, 66(12):5777-5784
	AAA	Douwes et al., "Biological agents – recognition," <u>Modern Industrial Hygiene</u> , Vol. 2, 2003, J.L. Perkins (ed.), ACGIH, Cincinnati, pp. 219-292
	ABB	Frick et al., " <i>Haemophilus influenzae</i> Stimulates ICAM-1 Expression on Respiratory Epithelial Cells," <u>J. Immunol.</u> , 2000, 164:4185-4196
	ACC	Ganz, "Antimicrobial polypeptides in host defense of the respiratory tract," <u>J. Clin. Invest.</u> , 2002, 109:693-697
	ADD	García et al., "Human β -defensin 4: a novel inducible peptide with a specific salt-sensitive spectrum of antimicrobial activity," <u>FASEB J.</u> , 2001, 15:1819-1821
	AEE	Giardina et al., "Construction of Acetate Auxotrophs of <i>Neisseria meningitidis</i> to Study Host-Meningococcal Endotoxin Interactions," <u>J. Biol. Chem.</u> , 2001, 276(8):5883-5891
	AFF	Gioannini et al., "Isolation of an endotoxin-MD-2 complex that produces Toll-like receptor 4-dependent cell activation at picomolar concentrations," <u>Proc. Natl. Acad. Sci. USA</u> , 2004, 101(12):4186-4191
	AGG	Gioannini et al., "An Essential Role for Albumin in the Interaction of Endotoxin with Lipopolysaccharide-binding Protein and sCD14 and Resultant Cell Activation," <u>J. Biol. Chem.</u> , 2002, 277(49):47818-47825
	AHH	Gioannini et al., "Regulation of interactions with endotoxin with host cells," <u>J. Endotoxin Res.</u> , 2003, 9(6):401-408
	AII	Gottar et al., "The <i>Drosophila</i> immune response against Gram-negative bacteria is mediated by a peptidoglycan recognition protein," <u>Nature</u> , 2002, 416:640-644
	AJJ	Hailman et al., "Lipopolysaccharide (LPS)-binding Protein Accelerates the Binding of LPS to CD14," <u>J. Exp. Med.</u> , 1994, 179:269-277
	AKK	Harder et al., "Mucoid <i>Pseudomonas aeruginosa</i> , TNF- α , and IL-1 β , but Not IL-6, Induce Human β -Defensin-2 in Respiratory Epithelia," <u>Am. J. Respir. Cell Mol. Biol.</u> , 2000, 22:714-721
	ALL	Harder et al., "Isolation and Characterization of Human β -Defensin-3, a Novel Human Inducible Peptide Antibiotic," <u>J. Biol. Chem.</u> , 2001, 276(8):5707-5713
	AMM	Harder et al., "A peptide antibiotic from human skin," <u>Nature</u> , 1997, 387:861

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(37 CFR §1.98(b))			

Other Documents (include Author, Title, Date, and Place of Publication)		
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	ANN	Higgins and Sharp, "Fast and sensitive multiple sequence alignments on a microcomputer," <u>CABIOS</u> , 1989, 5(2):151-153
	AOO	Higgins and Sharp, "CLUSTAL: a package for performing multiple sequence alignment on a microcomputer," <u>Gene</u> , 1988, 73:237-244
	APP	Hoffman et al., "Phylogenetic Perspectives in Innate Immunity," <u>Science</u> , 1999, 284:1313-1318
	AQQ	Huang et al., "Parallelization of a local similarity algorithm," <u>CABIOS</u> , 1992, 8(2):155-165
	ARR	Inzana et al., "Phase Variation and Conservation of Lipooligosaccharide Epitopes in <i>Haemophilus somnus</i> ," <u>Infect. Immun.</u> , 1997, 65(11):4675-4681
	ASS	Iovine et al., "The Carboxyl-terminal Domain of Closely Related Endotoxin-binding Proteins Determines the Target of Protein-Lipopolysaccharide Complexes," <u>J. Biol. Chem.</u> , 2002, 277(10):7970-7978
	ATT	Janeway Jr. and Medzhitov, "Innate Immune Recognition," <u>Annu. Rev. Immunol.</u> , 2002, 20:197-216
	AUU	Jia et al., "Discovery of new human β -defensins using a genomics-based approach," <u>Gene</u> , 2001, 263:211-218
	AVV	Jia et al., "Endotoxin responsiveness of human airway epithelia is limited by low expression of MD-2," <u>Am. J. Physiol. Lung Cell Mol. Physiol.</u> , 2004, 287:L428-L437
	AWW	Jiang et al., "Cutting Edge: Lipopolysaccharide Induces Physical Proximity Between CD14 and Toll-Like Receptor 4 (TLR4) Prior to Nuclear Translocation of NF- κ B," <u>J. Immunol.</u> , 2000, 165:3541-3544
	AXX	Karlin and Altschul, "Methods for assessing the statistical significance of molecular sequence features by using general scoring schemes," <u>Proc. Natl. Acad. Sci. USA</u> , 1990, 87:2264-2268
	AYY	Karlin and Altschul, "Applications and statistics for multiple high-scoring segments in molecular sequences," <u>Proc. Natl. Acad. Sci. USA</u> , 1993, 90:5873-5877
	AZZ	Karp et al., "An In Vitro Model of Differentiated Human Airway Epithelia," <u>Meth. Mol. Biol.</u> , 2002, 188:115-137
	AAAA	Kawasaki et al., "Involvement of TLR4/MD-2 complex in species-specific lipopolysaccharide-mimetic signal transduction by Taxol," <u>J. Endotoxin Res.</u> , 2001, 7(3):232-236
	ABBB	Kawasaki et al., "Identification of Mouse MD-2 Residues Important for Forming the Cell Surface TLR4-MD-2 Complex Recognized by Anti-TLR4-MD-2 Antibodies, and for Conferring LPS and Taxol Responsiveness on Mouse TLR4 by Alanine-Scanning Mutagenesis," <u>J. Immunol.</u> , 2003, 170:413-420
	ACCC	Lamping et al., "LPS-binding Protein Protects Mice from Septic Shock Caused by LPS or Gram-negative Bacteria," <u>J. Clin. Invest.</u> , 1998, 101(10):2065-2071
	ADDD	Latz et al., "Lipopolysaccharide Rapidly Traffics to and from the Golgi Apparatus with the Toll-like Receptor 4-MD-2-CD14 Complex in a Process That Is Distinct from the Initiation of Signal Transduction," <u>J. Biol. Chem.</u> , 2002, 277(49):47834-47843
	AEEE	Lehninger, "The amino acid building blocks of proteins," <u>Biochemistry</u> , 1975, 2 nd ed., pp. 73-75
	AFFF	Lemaitre et al., "The Dorsoventral Regulatory gene Cassette <i>spätzle/Toll/Cactus</i> Controls the Potent Antifungal Response in <i>Drosophila</i> Adults," <u>Cell</u> , 1996, 86:973-983
	AGGG	Lerman et al., "Nasopharyngeal Carriage of Antibiotic-Resistant <i>Haemophilus influenzae</i> in Healthy Children," <u>Pediatrics</u> , 1979, 64(3):287-291

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	AHHH	Liu et al., "Structure and mapping of the human β -defensin HBD-2 gene and its expression at sites of inflammation," <u>Gene</u> , 1998, 222:237-244
	AIII	Malley et al., "Recognition of pneumolysin by Toll-like receptor 4 confers resistance to pneumococcal infection," <u>Proc. Natl. Acad. Sci. USA</u> , 2003, 100(4):1966-1971
	AJJJ	Mathews et al., "Production of β -Defensin Antimicrobial Peptides by the Oral Mucosa and Salivary Glands," <u>Infect. Immun.</u> , 1999, 67(6):2740-2745
	AKKK	McCray, Jr. and Bentley, "Human Airway Epithelia Express a β -defensin," <u>Am. J. Respir. Cell Mol. Biol.</u> , 1997, 16:343-349
	ALLL	McCray, Jr. et al., "Alveolar Macrophages Inhibit Retrovirus-Mediated Gene Transfer to Airway Epithelia," <u>Hum. Gene Ther.</u> , 1997, 8:1087-1093
	AMMM	McNamara et al., "Ocular Surface Epithelia Express mRNA for Human Beta Defensin-2," <u>Exp. Eye Res.</u> , 1999, 69:483-490
	ANNN	Means et al., "The biology of Toll-like receptors," <u>Cytokine Growth Factor Rev.</u> , 2000, 11:219-232
	AOOO	Medzhitov and Janeway, Jr., "An ancient system of host defense," <u>Curr. Opin. Immunol.</u> , 1998, 10:12-15
	APPP	Medzhitov and Janeway, Jr., "Innate immune recognition: mechanisms and pathways," <u>Immunol. Rev.</u> , 2000, 173:89-97
	AQQQ	Medzhitov et al., "A human homologue of the <i>Drosophila</i> Toll protein signals activation of adaptive immunity," <u>Nature</u> , 1997, 388:394-397
	ARRR	Meinkoth and Wahl, "Hybridization of Nucleic Acids Immobilized on Solid Supports," <u>Anal. Biochem.</u> , 1984, 138:267-284
	ASSS	Miyake, "Innate recognition of lipopolysaccharide by CD14 and toll-like receptor 4-MD-2: unique roles for MD-2," <u>Int. Immunopharmacol.</u> , 2003, 3:119-128
	ATTT	Mueller-Anneling et al., "Ambient Endotoxin Concentrations in PM ₁₀ from Southern California," <u>Environ. Health Pers.</u> , 2004, 112(5):583-588
	AUUU	Mullen et al., "The role of disulfide bonds in the assembly and function of MD-2," <u>Proc. Natl. Acad. Sci. USA</u> , 2003, 100(7):3919-3924
	AVVV	Munford et al., "Biosynthetic radiolabeling of bacterial lipopolysaccharide to high specific activity," <u>J. Immunol. Meth.</u> , 1992, 148:115-120
	AWWW	Muroi et al., "MD-2, a Novel Accessory Molecule, Is Involved in Species-Specific Actions of <i>Salmonella</i> Lipid A," <u>Infect. Immun.</u> , 2002, 70(7):3546-3550
	AXXX	Muroi et al., "Regions of the Mouse CD14 Molecule Required for Toll-like Receptor 2- and 4-mediated Activation of NF- κ B," <u>J. Biol. Chem.</u> , 2002, 277(44):42372-42379
	AYYY	Myers and Miller, "Optimal alignments in linear space," <u>CABIOS</u> , 1988, 4(1):11-17
	AZZZ	Nagai et al., "Essential role of MD-2 in LPS responsiveness and TLR4 distribution," <u>Nat. Immunol.</u> , 2002, 3(7):667-672
	AAAAA	Needleman and Wunsch, "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins," <u>J. Mol. Biol.</u> , 1970, 48:443-453
	ABBBB	Newman, "Therapeutic aerosols," <u>Aerosols and the Lung</u> , 1984, Clarke and Pavia (eds.), pp. 197-224, Butterworths, London, England

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	ACCCC	Ohnishi et al., "N-Linked Glycosylations at Asn ²⁶ and Asn ¹¹⁴ of Human MD-2 Are Required for Toll-Like Receptor 4-Mediated Activation of NF-κB by Lipopolysaccharide," <u>J. Immunol.</u> , 2001, 167:3354-3359
	ADDDD	O'Neil et al., "Expression and Regulation of the Human β-Defensins hBD-1 and hBD-2 in Intestinal Epithelium," <u>J. Immunol.</u> , 1999, 163:6718-6724
	AEEEE	Pearson and Lipman, "Improved tools for biological sequence comparison," <u>Proc. Natl. Acad. Sci. USA</u> , 1988, 85:2444-2448
	AFFFF	Pearson et al., "Using the FASTA Program to Search Protein and DNA Sequence Databases," <u>Meth. Mol. Biol.</u> , 1994, 24:307-331
	AGGGG	Re and Strominger, "Monomeric Recombinant MD-2 Binds Toll-like Receptor 4 Tightly and Confers Lipopolysaccharide Responsiveness," <u>J. Biol. Chem.</u> , 2002, 277(26):23427-23432
	AHHHH	Re and Strominger, "Separate Functional Domains of Human MD-2 Mediate Toll-Like Receptor 4-Binding and Lipopolysaccharide Responsiveness," <u>J. Immunol.</u> , 2003, 171:5272-5276
	AIIII	Reynolds, "Integrated Host Defense Against Infections," <u>The Lung: Scientific Foundations</u> , 1997, Crystal et al. (eds.), Raven Press, Ltd., New York, NY, pp. 2353-2365
	AJJJJ	Schröder and Harder, "Human beta-defensin-2," <u>Int. J. Biochem. Cell Biol.</u> , 1999, 31:645-651
	AKKKK	Schromm et al., "Molecular Genetic Analysis of an Endotoxin Nonresponder Mutant Cell Line: A Point Mutation in a Conserved Region of MD-2 Abolishes Endotoxin-induced Signaling," <u>J. Exp. Med.</u> , 2001, 194(1):79-88
	ALLLL	Schütt, "Molecules in focus: CD14," <u>Int. J. Biochem. Cell Biol.</u> , 1999, 31:545-549
	AMMMM	Schutte and McCray, Jr., "β-Defensins in Lung Host Defense," <u>Annu. Rev. Physiol.</u> , 2002, 64:709-748
	ANNNN	Schutte et al., "Discovery of five conserved β-defensin gene clusters using a computational search strategy," <u>Proc. Natl. Acad. Sci. USA</u> , 2002, 99(4):2129-2133
	AOOOO	Shimazu et al., "MD-2, a Molecule that Confers Lipopolysaccharide Responsiveness on Toll-like Receptor 4," <u>J. Exp. Med.</u> , 1999, 189(11):1777-1782
	APPPP	Singh et al., "Production of β-defensins by human airway epithelia," <u>Proc. Natl. Acad. Sci. USA</u> , 1998, 95:14961-14966
	AQQQQ	Smith et al., "Endobronchial Infection in Cystic Fibrosis," <u>Acta Paediatr. Scand. Suppl.</u> , 1989, 363:31-36
	ARRRR	Smith and Waterman, "Comparison of Biosequences," <u>Adv. Appl. Math.</u> , 1981, 2:482-489
	ASSSS	Stryer, "Conformation and Dynamics," <u>Biochemistry</u> , 2 nd edition, W.H. Freeman and Co., San Francisco, 1981, pp. 14-15
	ATTTT	Takeda and Akira, "Toll receptors and pathogen resistance," <u>Cell. Microbiol.</u> , 2003, 5(3):143-153
	AUUUU	Tapping and Tobias, "Cellular Binding of Soluble CD14 Requires Lipopolysaccharide (LPS) and LPS-binding Protein," <u>J. Biol. Chem.</u> , 1997, 272(37):23157-23164
	AVVVV	Tauszig et al., "Toll-related receptors and the control of antimicrobial peptide expression in <i>Drosophila</i> ," <u>Proc. Natl. Acad. Sci. USA</u> , 2000, 97(19):10520-10525
	AWWWW	Thomas et al., "Evidence of a trimolecular complex involving LPS, LPS binding protein and soluble C14 as an effector of LPS response," <u>FEBS Lett.</u> , 2002, 531:184-188

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	AXXXX	Tsutsumi-Ishii and Nagaoka, "Modulation of Human β -Defensin-2 Transcription in Pulmonary Epithelial Cells by Lipopolysaccharide-Stimulated Mononuclear Phagocytes Via Proinflammatory Cytokine Production," <u>J. Immunol.</u> , 2003, 170:4226-4236
	AYYYY	Ulevitch and Tobias, "Recognition of Gram-negative bacteria and endotoxin by the innate immune system," <u>Curr. Opin. Immunol.</u> , 1999, 11:19-22
	AZZZZ	Ulevitch, "Molecular Mechanisms of Innate Immunity," <u>Immunol. Res.</u> , 2000, 21(2):49-54
	AAAAAA	Viriyakosol et al., "MD-2 Binds to Bacterial Lipopolysaccharide," <u>J. Biol. Chem.</u> , 2001, 276(41):38044-38051
	ABBBBB	Visintin et al., "Lysines 128 and 132 Enable LPS Binding to MD-2, Leading to Toll-like Receptor 4 Aggregation and Signal Transduction," <u>J. Biol. Chem.</u> , 2003, 278(48):48313-48320
	ACCCCC	Visintin et al., "Secreted MD-2 is a large polymeric protein that efficiently confers lipopolysaccharide sensitivity to Toll-like receptor 4," <u>Proc. Natl. Acad. Sci. USA</u> , 2001, 98(21):12156-12161
	ADDDDD	Wang et al., "Increasing Epithelial Junction Permeability Enhances Gene Transfer to Airway Epithelia <i>In Vivo</i> ," <u>Am. J. Respir. Cell Mol. Biol.</u> , 2000, 22:129-138
	AEEEEEE	Wang et al., "Toll-Like Receptor 4 Mediates Innate Immune Responses to <i>Haemophilus influenzae</i> , Infection in Mouse Lung," <u>J. Immunol.</u> , 2002, 168:810-815
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Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	